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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/235,986	01/22/1999	WAYNE A. HENDRICKSON	58323/JPW/PT	2152

7590 12/16/2005

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EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/235,986

Applicant(s)

HENDRICKSON ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 7-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Applicant's arguments filed 9/6/05 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6 have been cancelled.

Claims 7-13 are under consideration by the examiner.

Claim Rejections - 35 USC § 112

Claims 7-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 7 has been amended to recite "any available structural information." This is in contradiction to the specification at page 10 which specifically includes "proprietary structures determined by the process."

This also differs from the original claims and specification disclosure in that structural information and functional information is only included for proteins that have sequence information in the database whereas original claim 7 is directed to organizing all known structural information, sequence information, and functional information. That is, the structural and/or functional information for a protein could be present whether or not the sequence

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information is present. The database embraced by the instant claim does not have the same content as that contemplated by the original claims and specification disclosure.

Step (3) as disclosed at page 10 and in original claim 7 required synthesizing “in parallel simultaneously” which is absent from claims 7 and 13. These synthesized proteins were disclosed as needing to be from “appropriately representative species” which is absent from these claims.

Crystallization as disclosed at page 10 and in original claim 7 was to be done in parallel which is absent from claims 7 and 13.

With respect to claim 13, there is no contemplation of a method directed to maintaining a database followed by steps concerning clustering, cloning, and updating.

Steps (j)-(m) of claim 13 differ conceptually from steps (10)-(14) of the method disclosed on page 11.

A fair reading of the specification as originally filed would not convey to one of ordinary skill in the art that what is now claimed was the contemplated invention. Applicant may not recast or repackage the method steps originally contemplated into different combinations after the fact. The presently claimed methods as written are conceptually different from those claims originally filed and the methods disclosed in the specification as filed. The claims as presently written reword, rephrase, and select (by omission) the method steps as originally presented, and by doing so change the breadth and intent of the method as originally disclosed and claimed. They are not supported and constitute new matter.

Contrary to applicant's arguments, the disclosure is not flexible such that it can take on any of various configurations. The steps on pages 10-12 are not optional nor can limitations be included or excluded at will unless they are fairly contemplated by the originally filed disclosure.

Claim Rejections - 35 USC § 112

Claims 7-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some aspects of the claimed method and system, does not reasonably provide enablement for the breadth of what is encompassed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is maintained with for reasons of record.

The specification fails to guide one of skill in the art as to the particular steps to be performed and how they are to be performed in order to execute the method. For example, claim 7 recites "using at least one bioinformatics tool and the sequence information, structural information and functional information stored in the database." This does not illuminate which bioinformatic tool, what specific information, or how to use it to achieve the goal of clustering. It does not provide the positive, active steps to perform on unspecified structural or sequence information to arrive at a plurality of families within the context of the claims. For example, the database has sequence information for a first plurality of proteins and structural information and functional information for a second plurality of proteins. (Note that it is unclear if this is a partitioned database for the first and second plurality as they do not contain the same types of

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information.) For example, say the structural information for the second plurality is polymeric structure (monomer, dimer, etc.). For example, say the functional information for the second plurality is enzymatic activity (protease, synthase, etc.) How does one practicing the invention use polymeric structure and enzymatic activity to cluster into a plurality of families? For example, proteins A, B, and C are in the first plurality and proteins D, E, and F are in the second plurality. Protein D is a monomeric protease. Protein E is a trimeric synthase. Protein F is a monomeric protease. What is the plurality of families that the at least one bioinformatics tool identifies? How are homologous sequences for the family determined if the database does not contain sequence information for D, E, and F and their sequences cannot be compared to sequence information for A, B, and C? The specification provides no discussion or guidance for adapting bioinformatics tools to make such determinations. Going further in the claim to step (g), the refined model is stored in the database. Note that part (a) does not require that the structural information include a refined model or a homology model. Going further in the claim to step (j), the database is updated to link the refined model to other databases. Note that part (a) does not require that the database have links to any information at all. The method steps as written are internally inconsistent. As written, one of ordinary skill in the art would be unable to practice the method for at least these reasons.

Likewise, claim 13 is similarly not enabled as it parallels claim 7. In addition, there is no guidance for how steps (k)-(m) are to be performed by one of ordinary skill in the art.

The claims are interpreted in view of the specification without importing limitations from the specification into the claims. As such, the specification must enable the full breadth of what is embraced by the claims and not merely some aspects of the claims.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These rejections are maintained for reasons of record with respect to “homologous sequences” and “families.” The claims are unclear as to what level of homology defines a family and applicant’s claims are not limited to the “30% identity, <0.001 probability of error” recited in the arguments. The specification provides no limiting definition and there does not appear to be an art understood definition. The specification and claims fail to make clear what level of homology constitutes a family for the purposes of their invention.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712.

The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Marianne P. Allen
Primary Examiner
Art Unit 1647

12/12/05

mpa